

Rejections previously made under §§112 and 103 based on Jackson only have been withdrawn, so these previous and now withdrawn rejections need not be further addressed.

Claims 19 and 27 have been finally rejected as obvious under §103 from Jackson in view of Schlipalius for reasons previously applied. This rejection is respectfully traversed for the reasons of record, respectfully repeated by reference, and for the following reasons as well.

Claims 19 and 27 both require that the "unit dosage form composition" recited in the claimed method have "as active ingredients **only** a phytoestrogen in a physiologically effective amount as an HRT agent", and "a combination of carotenoids comprising lycopene and at least one of phytoene and phytofluene," as recited in claim 19 (emphasis added).

Jackson, the main reference "relates to dietary supplements formulated to supplement a woman's specific micronutrient and phytochemical needs during each of her adult life stages, ..." col. 1, lines 5-7. Jackson further states (col. 2, lines 13 *et seq.*) that even though "the etiology of disease is multi-factorial, certain dietary supplements have been shown to provide a statistically significant benefit in reducing the risk or reducing the incidence of various diseases and conditions."

In a first embodiment, Jackson suggests a composition (col. 2, line 40 *et seq.*) "comprising about 100 to about 500 mg calcium, about 100 to about 200 mg magnesium, about 0.5 to about 1.5 mg boron, about 0.5 to about 1.5 copper, about 2 to about

2.6 mg manganese, about 10 to about 13 mg zinc, about 200 to about 300 i.u. Vitamin D, about 12 to about 18 iron, about 400 to about 440 µg folic acid, about 2 to about 10 µg Vitamin B₁₂, about 50 to about 100 mg Vitamin B₆, about 50 to about 100 µg chromium, about 100 to about 200 i.u. Vitamin E, about 100 to about 1000 mg Vitamin C, and about 8 to less than 50 phytoestrogen in admixture with a biologically acceptable carrier."

There can certainly be no doubt that Jackson absolutely does **not** teach or suggest administering a unit dosage form composition having as active ingredients only (1) at least one of phytoestrogen and (2) a combination of carotenoids comprising lycopene and at least one of phytoene and phytofluene, as claimed. Jackson requires many active ingredients, not only what is called for in Applicants' claims. Applicants have flown in the face of the teachings of Jackson.

In a second embodiment of Jackson (col. 2, line 52 to col. 3, line 4), Jackson sets forth another formulation containing a plurality of active ingredients (col. 2, line 59 et seq.) including calcium, magnesium, boron, copper, manganese, zinc, Vitamin D, iron, folic acid, etc. Again, it is absolutely clear that Jackson teaches and suggests that the reader of Jackson must incorporate into the composition a large number of active components which are excluded by Applicants' claims.

In a third embodiment (col. 3, lines 5-21), Jackson again instructs those wishing to follow the teachings of the Jackson patent to use calcium, magnesium, boron, copper, manganese, zinc, Vitamin D, iron, folic acid, Vitamin B₁₂,

Vitamin B₆, chromium, Vitamin E, Vitamin C, and the phytoestrogen "in admixture with a biologically acceptable carrier." There can be no doubt that Jackson teaches that one must use a plurality of active components, contrary to what is required according to Applicants' claims 19 and 27.

One cannot follow the teachings of Jackson without doing what Jackson says is to be done, and Applicants have claimed a method for administering a composition which does not do what Jackson says must be done. One cannot learn to follow the present invention by reading Jackson.

The position of the PTO is that it would have been obvious to modify Jackson from a consideration of Schlipalius, but Applicants respectfully but strenuously dispute this conclusion, because Schlipalius is simply silent regarding any multi-active component composition. Thus Schlipalius does not say that one should ignore all the components of Jackson, or anything else which would lead to such a conclusion. Schlipalius only discloses a composition comprising (1) a carotenoid, (2) a dispersion of a water disperable matrix and a stabiliser, and optionally a non-oil solvent, and (3) an emulsifier (see abstract of Schlipalius).

Thus, one reference (Jackson) discloses compositions containing many active ingredients, whereas the number of active ingredients is limited according to Applicants' claims; and the other reference (Schlipalius) teaches a composition containing only one active ingredient. Neither reference requires only two types of active ingredients, and neither reference recognizes or teaches the important of the utilization of the two types of

active ingredients required according to Applicants' claims, or what the effect might be of the use of just these two types of components.

(Incidentally, Applicants respectfully dispute the examiner's comments at the end of the second paragraph on page 3 of the Final Action to the effect that the teaching of "lutein" meets the Markush Grouping of claim 23, as claim 23 is not presently pending, and was not pending at the time the Final Rejection was made.)

At the end of the third paragraph on page 3 of the Final Action, the examiner takes the position that Jackson suggests that hormone replacement therapy contributes to the reduction of some forms of cancer. However, Applicants' claims call for a method "for reducing the risk of developing cancer associated with hormone replacement therapy (HRT), comprising administering to a woman in need thereof" the unit dosage form composition specified in Applicants' claims. Accordingly, the examiner's commentary does not apply, as it is well known and well accepted that HRT presents a risk of uterine cancer and breast cancer, and possibly also ovarian cancer. Applicants' have made no claim for and do not claim that the present invention reduces the risk of developing all kinds of cancer in all types of people from all causes. Thus, the Examiner's quotation in the bottom line on page 3 of the Final Action is incomplete, as the method claim is "for reducing the risk for developing cancer **associated with hormone replacement therapy.**"

With respect to page 4, first paragraph of the Final Action, Applicants are claiming "only" the recited components.

This must be contrasted with what the prior art teaches or suggests. Those skilled in the art reading Jackson can only conclude that one must not use **only** the active ingredients recited in applicant's claims. It is not proper to use an applicant's specification as part of rejection against the applicant's own claims, *In re Schulpen*, 157 USPQ 52, 55; *In re Ruff et al*, 118 USPQ 340, 346; *Ex Parte Horn et al*, 145 USPQ 719; *In re Irani et al*, 166 USPQ 24, 26. An applicant may retreat to the applicant's "preferred" invention, even though the disclosure is broader, *In re Saunders et al*, 170 USPQ 213, 220.

Moreover, to say that the language of the claims is not closed, and/or that one must use "consisting of" to provide closed language, makes no sense in view of the express use of the word "only" in Applicants' claims. Applicants respectfully but strongly traverse brushing aside clear language of the claims and refusing to give such language full weight.

As regards claim 27 and the Examiner's arguments in the bottom paragraph on page 4 of the Final Action, Applicants believe and respectfully but submits that the evidence of record is adequate to establish the importance of the parameters recited in the claim 27.

As regards the Examiner's conclusion at the end of the top paragraph on page 5, Applicants respectfully note that there is a difference between what Jackson states is necessary (see the three examples of Jackson's required ingredients referred to above), and what Jackson states is optional, namely "an amount of vitamin A or mixed carotenoids..." The Examiner brushes

aside the required active ingredients of Jackson, and emphasizes the optional ingredients. The person of ordinary skill in the art, reading Jackson, is guided to use those components which Jackson says are necessary, and to view the optional ingredients as not being part of what Jackson recommends.

As regards the Examiner's commentary on page 7 of the Final Action, the Examiner appears to confuse obviousness with inherency. The fact that something may be inherent does not make it obvious. Applicants have claimed an unobvious result, and it has not been demonstrated that the result (even if it later turned out to be inherent) was obvious at the time Applicants' invention was made.

In this regard, the argument made by the Examiner appears to be based on the assumption that the Applicants' claimed method is not novel, i.e. it is anticipated by Jackson. But there is no rejection under §102 and no evidence that anyone ever did what Applicants are claiming. If no one did it, it cannot have been inherently done. Thus, any result produced by such a previously not completed method cannot have been inherently produced. (On the issue of the difference between obviousness and inherency, please see *In re Rijckaert*, 28 USPQ2d 1955, 1957 and decisions at page 1957; *In re Henderson*, 146 USPQ 372, 375; and *In re Shetty*, 195 USPQ 753, 756-57.) What was later discovered to have been inherent does not make obvious what an applicant teaches or claims.

Returning to Examiner's reliance on Schlupalius, the disclosure relied upon at column 3, lines 10-19 is a "basket" or

"shot gun" disclosure which does not lead one skill in the art to select the combination of carotenoids recited in Applicants' claims.

In this respect and as regards the bottom paragraph on page 8 of the Final Action, the disclosure of Schlupalius concerning combinations of carotenoids is only very general, and itself constitutes a basket or shot gun disclosure, there being 15 specific carotenoids listed, in addition to fat soluble retinoids and natural carotenoid isolates, in addition to mentioning possible mixtures as only an option and with no indication of which mixtures. Respectfully, the Examiner has extrapolated far too much from the reference, and has proceeded on the basis of knowledge of Applicants' disclosure, not what the person of ordinary skill in the art would have known at the time the present invention was made. It is clear that the permutations and combinations, considering all the listed options, and whether or not mixtures are present, is very large indeed, and so large as to give the person skilled in the art no guidance as to which mixture (if any) is to be selected.

The combination of Jackson in view of Schlupalius does not obviously lead the person of ordinary skill in the art to the method set forth in Applicants' claims. Withdrawal of the rejection is in order and is respectfully requested.

In re Appln of Joseph LEVY et al
Appln. No. 10/825,434
Reply to Final Rejection of July 7, 2010
Amendment dated December 15, 2010

If the Examiner has any questions or suggestions, he
is respectfully requested to contact the undersigned at (202)
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Respectfully submitted,

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